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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,263	07/12/2001	Mary Ellen Rybak	OC01000KQ	3021

24265 7590 06/29/2004

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,263	RYBAK ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-17 and 21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7, 9-17 and 21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/19/2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Oct. 10, 2003, as well as the IDS filed 4/19/2004 has been entered.

2. Claims 1, 3-7, 9-17 and 21-40 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained:

4. The rejection of claims 1, 3-7, 9, 11, 12, 14-17 and 21-40 under 35 U.S.C. 103(a) as being unpatentable over Kirkwood et al (Kirkwood, J.M. et al., J. Clinical Oncol. 14(1): 7-17, 1996; cited in the IDS) in view of Gilbert et al (U.S. 5,951,974; issued Sep. 14, 1999; filed Dec. 19, 1997; cited in the IDS), in view of Glue et al (U.S. 5,908,621; issued June 1, 1999; filed Apr. 29, 1997; cited in the IDS), and further in view of Talpaz et al (Blood, 92(10): 1998, page 251a; cited in the IDS) is maintained for the reasons of record.

As currently amended claims 1, 3-7, 9, 11, 12, 14-17 and 21-40 are drawn to methods of treating patients having melanoma with pegylated interferon alpha, or interferon alpha-2b, wherein the pegylated interferon alpha is administered within specific dose ranges or at specific dosages. Applicants have provided a declaration by Dr. Craig Tendler, filed under 37 C.F.R. 1.132 to substantiate the assertion that the arrival at an optimum dose range for pegylated interferon alpha is an unexpected result. In the declaration Dr. Tendler states that the pegylation of interferon alpha increases the half-life of interferon alpha, and that this increase in half-life significantly alters certain pharmacokinetic properties of interferon alpha. Specifically, the relationship of peak plasma levels to total drug exposure (AUC) is different for interferon alpha compared to that of unpegylated interferon alpha, and that administration of pegylated interferon alpha as compared to unconjugated interferon alpha results in lower peak plasma levels of interferon alpha activity but prolongs total drug exposure as compared to administration of unconjugated interferon alpha.

In response, it is noted that the decrease in peak plasma levels due to pegylation of interferon alpha appears to be true only for some forms of pegylated interferon alpha (see Gilbert, col. 13-col.14, Table 5). While the peak plasma level (Cmax) for sample A is decreased from what it is for native interferon alpha, the peak plasma level appears to be slightly increased for sample C. Applicant has based the argument for unexpected results on the fact that in the treatment of melanoma, the peak plasma level appears to be most important for a therapeutic effect, and that given the fact that the total exposure to interferon alpha is increased by pegylation, while peak plasma level is decreased by pegylation, one of ordinary skill in the art would not have had a reasonable expectation of success in determining the optimum dose level because it might have been the case that the optimum dose level for achieving a peak plasma level would have been one that induced unacceptable side effects due to the great increase in total exposure. However, this argument appears to be relevant to some forms of pegylated

interferon and not for others, and the claims are not limited to those forms for which this argument applies. Thus, the declaration is not commensurate in scope with the scope of the claimed inventions. Therefore, the rejection of the claimed inventions is maintained for the reasons of record.

9. The rejection of claims 1, 3-7, 10, 11, 13, and 14 under 35 U.S.C. 103(a) as being unpatentable over Creagan et al (Creagan et al., J. Clinical Oncol. 13(11): 2776-2783, 1995) in view of Gilbert et al (U.S. 5,951,974; issued Sep. 14, 1999; filed Dec. 19, 1997), and further in view of Glue et al (U.S. 5,908,621; issued June 1, 1999; filed Apr. 29, 1997) is maintained for the reasons of record.

Claims 1, 3-7, 10, 11, 13, and 14 are drawn to methods of treating patients with a surgically removed melanoma comprising administering pegylated interferon alpha or interferon alpha-2a, wherein the pegylated interferon alpha is administered within specific dose ranges or at specific dosages. Applicant argues that none of the cited references teach the specific dose ranges or dosages, and that it would not be obvious for one of skill in the art to arrive at the claimed dose ranges or specific dosages, and that the art of record fails to provide a reasonable expectation of success in achieving the claimed inventions.

As discussed above, the declaration filed, which asserts unexpected results, is not commensurate in scope with the scope of the claims. Therefore, the rejections of the claims are maintained for the reasons of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
June 25, 2004

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
6/28/2004